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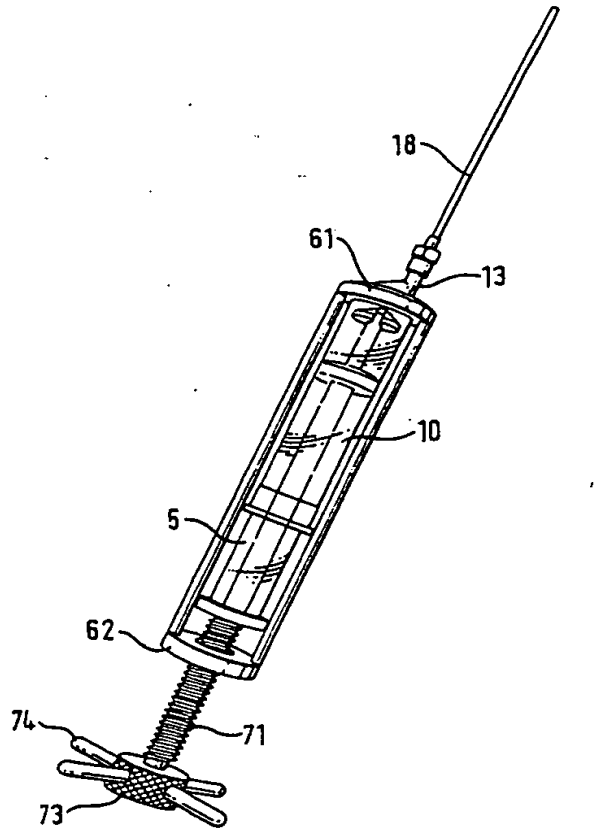
(54) Title: AN APPARATUS FOR MIXING AND DISPENSING INGREDIENTS

(57) Abstract

An apparatus which is particularly useful for the mixing of hydroxyapatite cement comprises a syringe body (10) within which a plunger (5) is slidably and sealingly located for expelling the syringe contents, the plunger having an axial passageway and the shaft (2) of an agitator (4) extending therethrough. The agitator has a head portion (25) designed to cause materials (8) contained in the chamber defined between the inner end of the plunger and the syringe interior to be mixed when the actuator is agitated by manual operation of the agitator shaft where it is accessible outside of the plunger. To facilitate dispensing of the mixture, the apparatus can be received in a support frame (60) having a turnscrew (72) at one end enabling the plunger to be operated with mechanical advantage. A removable end cap (16) seals the mixing chamber (8) during mixing and the mixture can be dispensed through an elongate tube into limited access locations.



AN APPARATUS FOR MIXING AND DISPENSING INGREDIENTS

Field of the Invention

This invention relates to an apparatus for mixing and dispensing ingredients, particularly though not exclusively for mixing and dispensing hydroxyapatite cement.

Background of the Invention:

It is well known to use hydroxyapatite cement (hereinafter also referred to as BoneSource (Registered Trade Mark)) to fill any non-load bearing bone void with the exception of those anatomical areas contacting the central nervous system or central circulatory system of the human body.

The preparation of BoneSource hydroxyapatite cement requires that immediately prior to application into a bone void, BoneSource powder is mixed with a liquid curing agent under sterile conditions. The mixing of these ingredients is usually achieved by manually stirring of the ingredients in a beaker until a doughy consistency has been obtained. Typically, a 10 gram package of BoneSource powder is mixed with 2.5 to 3.0 mls of a liquid curing agent.

It is well known to apply the mixed BoneSource to a bone void by forming a ball of the doughy mixture with the fingers and then manually packing the doughy mixture into the void from the most convenient point on the external surface of the bone in the region of the fracture.

Such a mixing process has proven to be both wasteful and difficult to operate because powder or liquid may be spilled from the beaker during mixing, proportions of the ingredients which are to be mixed may not be completely mixed and the doughy consistency required of the mixed ingredients may vary. In addition, there are certain surgical procedures for which access to the bone void into which the BoneSource is to be applied is severely limited.

container may be dispensed, and a plunger sealingly engaged in said container and movable axially thereof, the agitator shaft being arranged to pass substantially sealingly through an aperture in the plunger.

The cylindrical container can conveniently comprise a standard syringe body and the plunger can conveniently comprise a substantially standard syringe plunger formed with an elongate passage therethrough for the agitator shaft. An elongate dispensing tube may be connectable to the nozzle of the syringe to enable the mixed syringe contents to be accurately dispensed into difficult locations.

To facilitate dispensing of the mixed syringe contents which, as aforementioned, may have a relatively stiff consistency, a support means for the syringe may be provided, the support means having provision for operating the plunger of the syringe with a mechanical advantage. In the hereinafter described embodiment, the support means is a frame within which the syringe may be received with a manually operable turnscrew mounted in the frame and bearing upon the plunger for moving the plunger inwardly of the syringe body to dispense the mixed constituent materials through the nozzle of the syringe.

The abovementioned embodiment of the present invention will now be described by way of example with reference to the accompanying drawings.

Description of the Drawings:

Figure 1 is a side elevation view of a mixing and dispensing device in accordance with the present invention;

Figure 2 is a side elevational view of the device of Figure 1 together with a means for facilitating dispensing of the mixed contents from the device;

Figure 3 is a view similar to Figure 2 but in which the end cap of the device has been replaced by a dispensing tube;

Figure 4 is an external view of the end cap which is mountable on the device to seal it during mixing;

A dispensing plunger 5 is slidably located within the body 1. A seal 6 is mounted on the innermost end 7 of the plunger to define at the closed end of the body a sealed chamber 8 within which the ingredients to be mixed may be mixed in a sealed sterile environment. Conveniently, the mixing of the ingredients within a sealed chamber has the effect of ensuring that none of the ingredients are spilled irrespective of the force which is applied in agitating the ingredients within the chamber.

The body 1 comprises an elongate tubular casing 10 closed at one end 11 and may be constituted by the outer tube of a standard 20ml medical syringe including radially outward pressure flanges 12 at the open end thereof and a luer outlet nozzle 13 extending outwardly from the closed end 11. The outlet 13 has a central passageway therethrough which communicates with the interior chamber 8 of the tubular casing 10 and has an external shape enabling a luer slip closure cap 16 having a knurled head 17 (Figure 4) to be friction coupled thereto for closing off the outlet. The cap 16 can be removed and replaced by an elongate dispensing tube 18 (Figure 3) enabling the mixed product to be dispensed from within the casing 10 into a relatively inaccessible location. The cap 16 has an embedded pin 19 which projects therefrom as shown in Figure 4 and fits into the outlet nozzle 13 of the syringe when the cap 16 is fitted so as to avoid dead space within the outlet nozzle.

The plunger 5 is illustrated in more detail in Figure 7(a) and is substantially a modified form of the usual plunger used in a surgical syringe, the modification being the provision of an elongate central aperture 40 extending through the plunger along an elongate central axis 41 of the plunger for receiving the agitator paddle 2 therethrough. A seal 42, preferably a hollow rubber seal as shown in Figure 7(b), is mounted on the innermost end 43 of the plunger which is inserted in the tubular casing. The seal 42 has an annular inwardly extending flange 44 at a location within the hollow seal corresponding to a recessed groove 45 located in external surface 46 of the seal. A major open end face 47 of the seal, when mounted on the plunger, is

base of head 25 is substantially identical with the internal diameter of the tubular casing so as to provide a snug fit therein, but not a sealed fit. Four slots 29 are provided through the head, each being angularly displaced from the next by 90°. The slots 29 have the effect of allowing, in use, sufficient shear forces to be applied to the constituents being mixed so as to effect efficient mixing thereof within chamber 8.

A diametrically extending aperture 30 is located through the agitator rod, towards outermost end 22 of the paddle 2 for receiving bar 4 as seen in Figure 6, the bar 4 having a spherical head 31 from which extends an elongate rounded shaft with a small taper lead 32 at end 33 remote from the spherical head to enable ease of entry into the transverse aperture 30 in the agitator paddle 2. The presence of the bar 4 facilitates movement of the agitator paddle 2 in the longitudinal and/or rotational directions to mix the constituent materials placed into the tubular casing.

Figures 8 and 9 illustrate a syringe holder 60 comprising two opposed end members 61, 62 spaced apart by two elongate spacers 63. The elongate spacers 63 are each fixedly attached at their opposite ends to the end members 61, 62.

One end member 61, the right-hand end member in Figure 8, comprises an annular outer support portion 65 which has an inwardly projecting annular flange 66 extending outwardly of the holder in an axial direction thereof with a central aperture 67 therein. The opposite end support 62 comprises a circular plate having a centrally located internally screw-threaded aperture 68 therein with a relatively small radially extending slot 69 which extends into the central aperture of the end support from external circumferential surface 70. The width of the slot is sufficient to receive therethrough the agitator paddle 2.

A pressure screw 71 is shown in Figure 9 and has a screw threaded shank 72 which is adapted to be screw threadedly engaged with the internally threaded aperture 68 in end support 62 of the syringe holder 60. The shank 72

moved in the longitudinal direction of the paddle to cause mixing of the powder/liquid constituents.

Dry unmixed powder will offer considerable resistance to the movement of the agitator rod. This will decrease as the mixture becomes more thoroughly mixed. Complete mixing is achieved when the agitator paddle can be moved through the BoneSource from one end to the other of the mixing chamber. The mixture at this point should have a consistency similar to that of toothpaste.

In the event that complete mixing is not achieved or that the consistency is more viscous than desired, up to 0.5 mls of liquid curing agent can be further added. This may be achieved by removing the end cap from the luer outlet nozzle and introducing the liquid curing agent by means of a conventional syringe with a needle. Before remixing the ingredients the end cap must be replaced. It is possible to add additional liquid curing agent dropwise until a desired consistency is obtained. However, it is essential to avoid adding too much fluid which may result in the mixed product being insufficiently viscous. The agitator paddle is then pulled sharply back onto the seal of the plunger to clear any excess mixture located between the agitator head and the seal and ensure that the agitator head 21 does not obstruct the nozzle outlet opening.

The end cap 16 may then be removed and the plunger depressed manually to extrude BoneSource from the luer output nozzle 13 directly to the site of application. If the application site has restricted access, a tube 18 of needle dimensions and having a female luer connector can be mounted upon the male luer output nozzle 13 to facilitate application of the BoneSource mixture.

If the female luer connector 18 is mounted on the tubular casing outlet nozzle 13, the narrow tubular nature of the connector may be such as to increase the back pressure within the tubular casing 10 to such an extent that it becomes difficult to extrude the mixed product. In this instance it is

other parts such as the syringe may be made of plastics or rubber material. In this respect, the metal parts, in particular the agitator paddle 2, bar 4, holder 60 and pressure screw 71 are preferably of highly polished stainless steel. The remaining parts are preferably of polypropylene or other materials commonly used for construction of medical devices, other than the seal 43 which is of a rubber material which may be a synthetic rubber or a natural rubber material.

Whilst the invention has been described in the foregoing by reference to a specific embodiment, it is to be appreciated that the described embodiment is exemplary and that modifications and variations thereto can readily be made without departure from the spirit and scope of the invention as set forth in the appended claims. For example, as shown in Figures 10 and 11 the end cap can advantageously be manufactured as a two piece assembly to facilitate cleaning and sterilization, the two pieces 100 and 101 being shown separately in Figure 10 and being shown in use in Figure 11 attached to the outlet nozzle 13 of the syringe body 10. Furthermore, the head of the agitator could be modified, for example as shown in Figures 12a and 12b where there are four additional shorter slots between the slots of the agitator head as shown in Figure 5b. Another possible modification would be to provide an additional spacer 63 in the syringe holder of Figure 8 or to form an equivalent spacer structure of sheet metal.

6. An apparatus as claimed in any of claims 2 to 5, wherein the limited region (20) is intermediate the opposite ends of the agitator shaft and includes reduced thickness portion having a flat surface to provide a gap between the agitator shaft and the second relatively movable portion to facilitate passage of gas from the mixing chamber.

7. An apparatus as claimed in any preceding claim, wherein the dispensing means comprises sealing means for sealing contact with the walls of the mixing chamber to seal the chamber.

8. An apparatus as claimed in any preceding claim, wherein the dispensing means comprises a plunger (5) and the agitator means (2) is arranged to pass sealingly through an aperture in the plunger.

9. An apparatus as claimed in any preceding claim, wherein the chamber (8) has an outlet through which mixture within the chamber can be dispensed.

10. An apparatus as claimed in claim 9, wherein the outlet is a luer outlet (13).

11. An apparatus as claimed in claim 9 or 10, wherein the chamber outlet (13) has an externally applied cap (16) for sealing the outlet when mixing the materials.

12. An apparatus as claimed in claim 9 or 10, wherein an elongate dispensing tube (18) is mounted to the outlet externally of the chamber to enable mixed materials to be dispensed into limited access locations through the tube to facilitate packing of a bone void into which the tube can be directed.

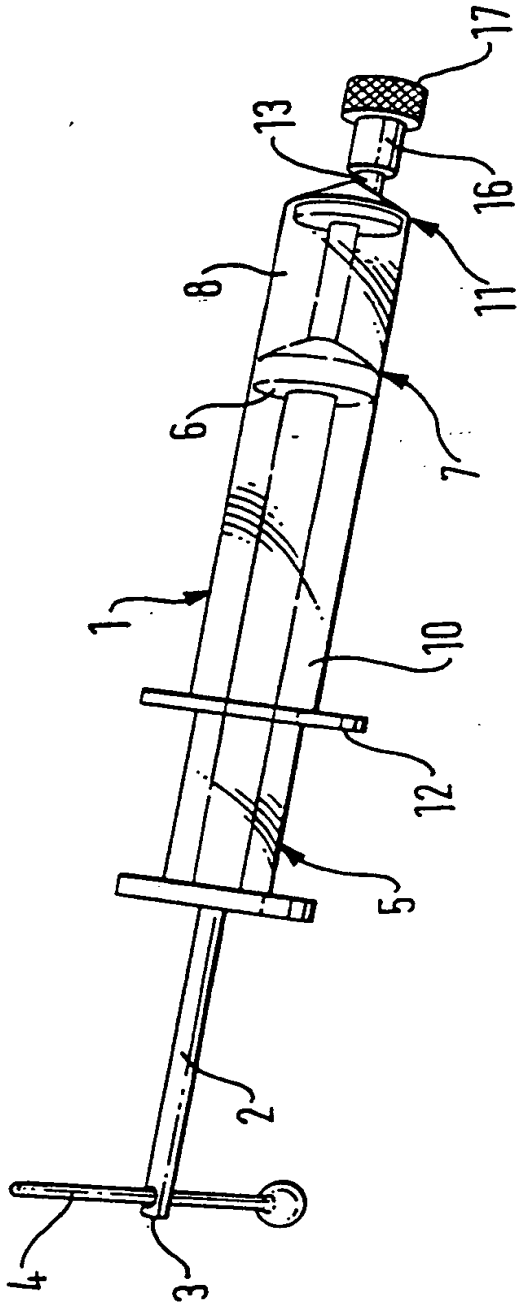
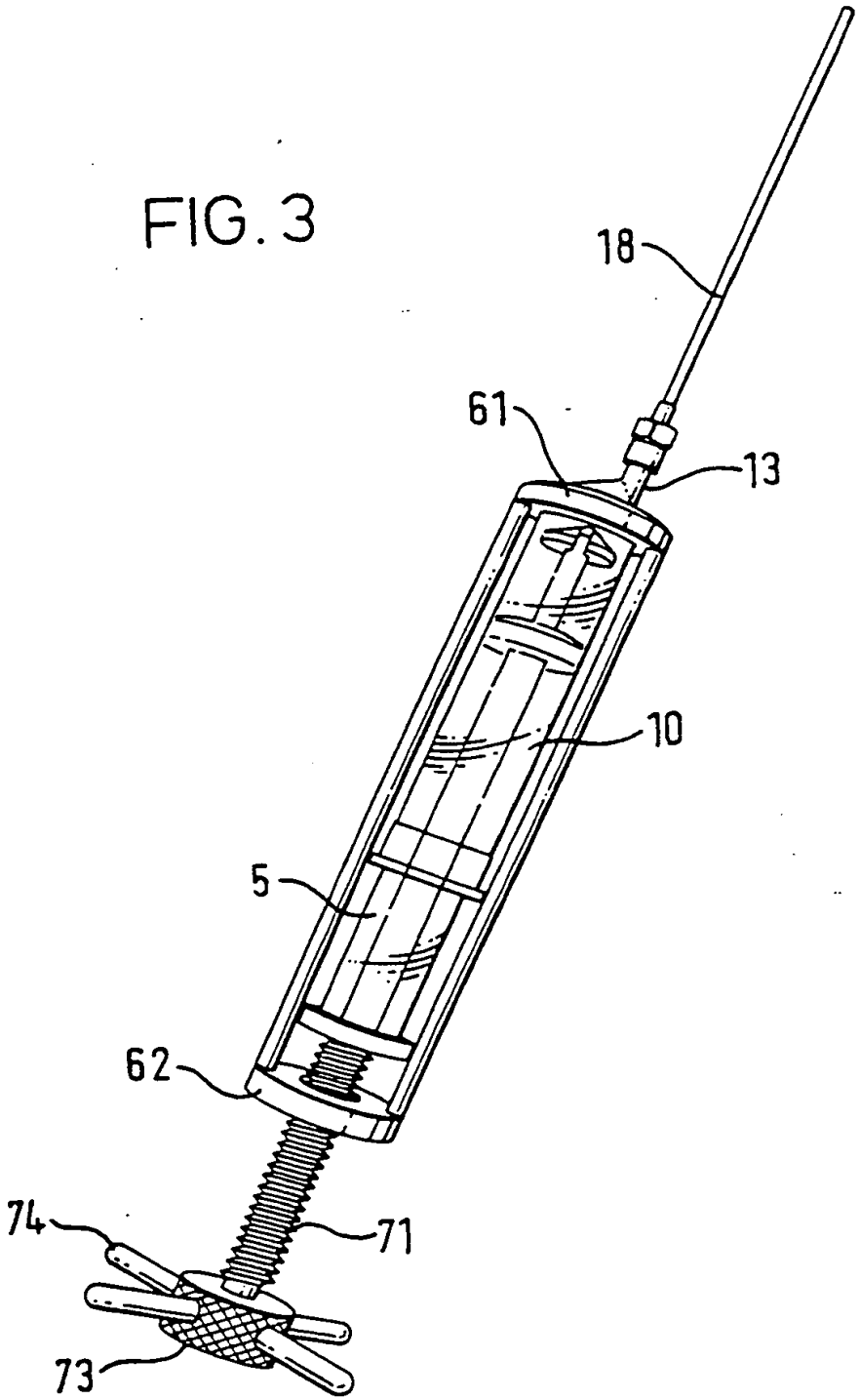


FIG. 1

FIG. 3



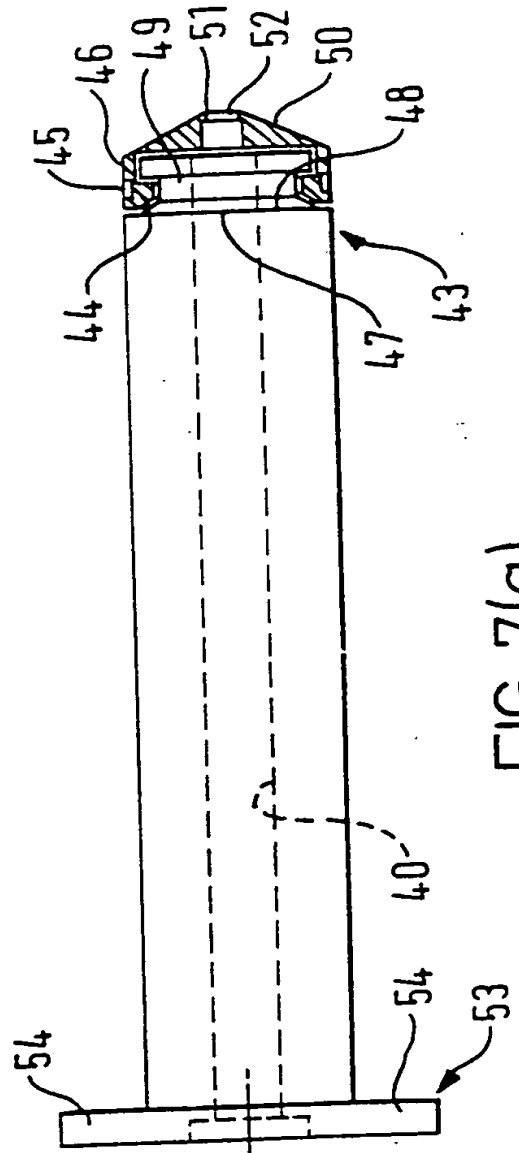


FIG. 7(a)

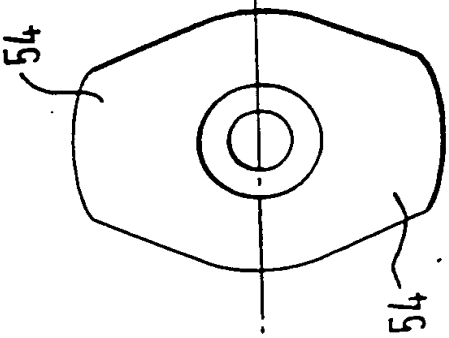


FIG. 7(b)

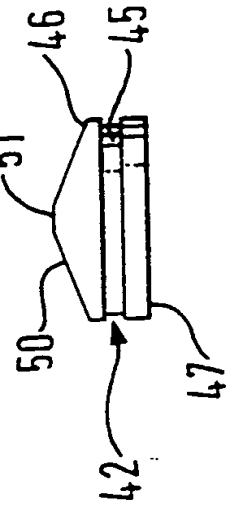
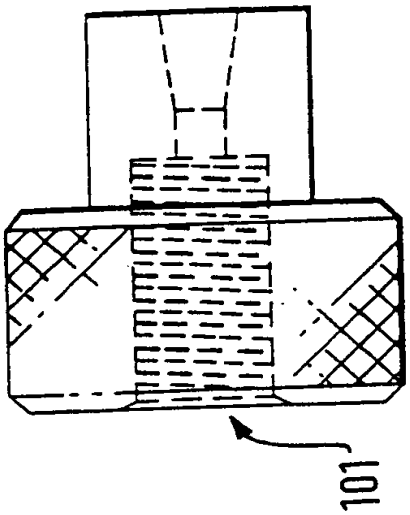


FIG. 7(c)



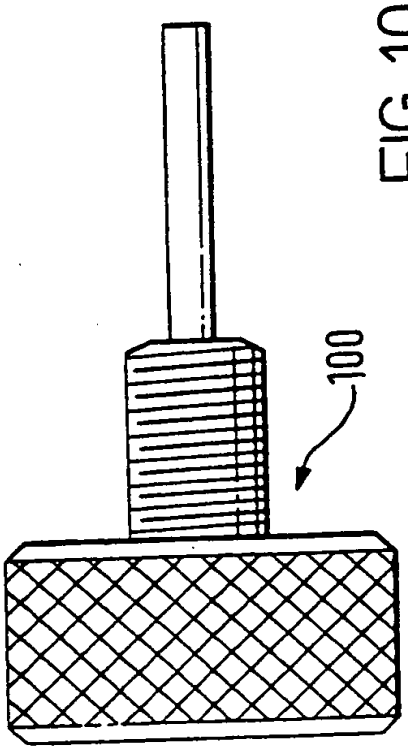


FIG. 10

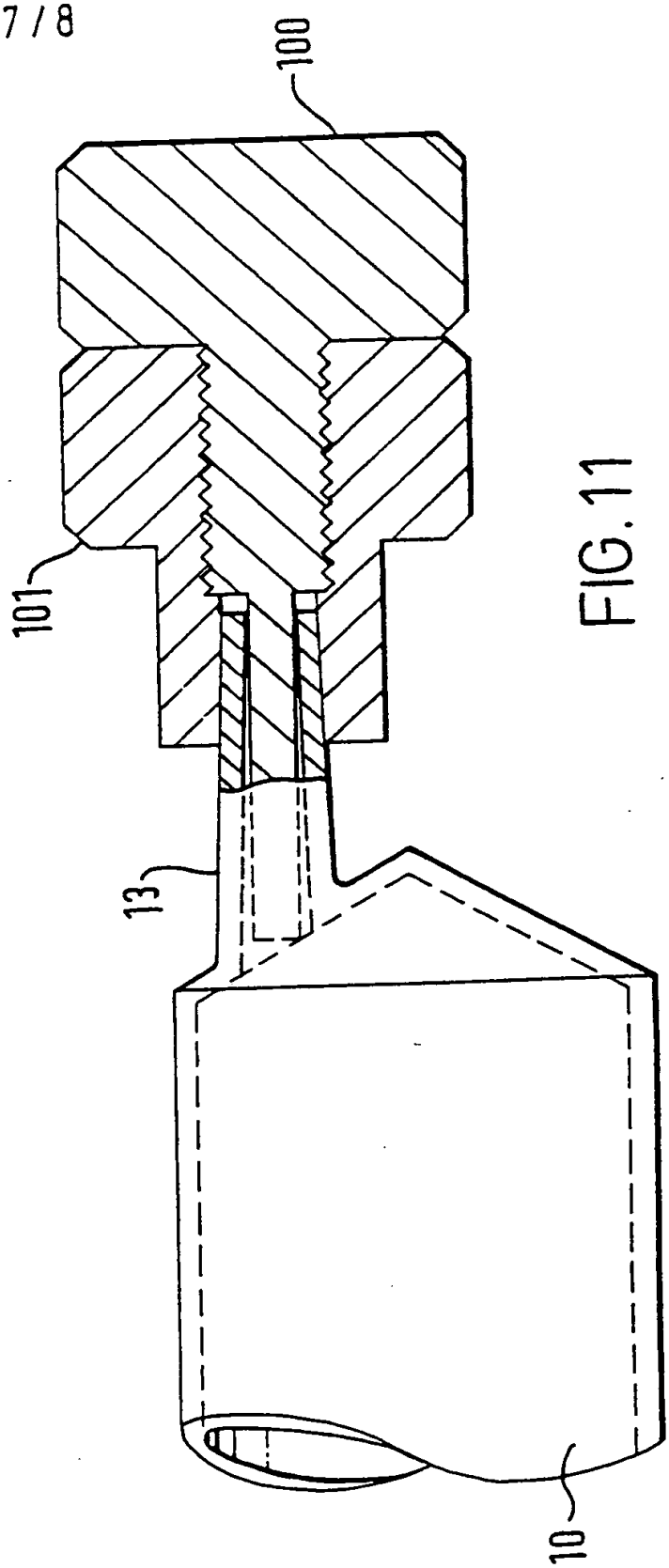


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 99/01922

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: B01F 3/12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: B01F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC, PAJ, US FULLTEXT

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3546129 A (ROBERT H. BERG ET AL), 8 December 1970 (08.12.70), column 2, line 57 - column 3, line 6, figures 1,3	1-3,9-11,14
X	GB 1340483 A (THE BRITISH UNITED SHOE MACHINERY COMPANY LIMITED), 12 December 1973 (12.12.73), page 2, line 70 - page 3, line 43, the figure	1,2,9-11,14
A	US 5252301 A (THOMAS NILSON ET AL), 12 October 1993 (12.10.93), column 1, line 5 - line 15; column 2, line 45 - line 68, figures 2-4	1-17

☐ Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
4 October 1999	03. 11. 1999

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